Holland Bloorview
Kids Rehabilitation Hospital

Bloorview
RESEARCH INSTITUTE

eREB New Study Submission Required Documents

Documents for All Study Types
Study Protocol Must include a version date and a field to record REB number e.g. Version dated DD/MM/YYYY eREB# XXX (see REB SOP 301.003 on HB REB website for protocol section requirements)
Study Budget
Signed *Scientific Review Form* and itemized response to comments from reviewer(s)
Research Team Training Certificates TCPS2, CITI Modules: RCR, Privacy - Canada
Departmental Approval Form For research involving clients at Holland Bloorview [found on HB Connect] (if applicable)
Informed Consent Forms (ICF) and Assent Forms Must use ICF and Assent Templates on the HB REB website (if applicable)
Capacity Assessment Documents (if applicable)
BRI 'Participate in Research at Holland Bloorview' Flyer (if applicable)
BRI 'Participate in Research at Holland Bloorview' webpage information Must use CMS Template on the HB REB website (if applicable)
connect2research Recruitment Materials Provide a decision letter from the Connect2research office; include all letters, scripts, and emails that will be used to contact participants (if applicable)
Participant Facing Documents All documents that will be given to, read to, or seen by participants including recruitment materials, phone/email scripts, questionnaires/ surveys, outcomes measures, screening forms, data collection forms, diaries, interview guides, videos, Volunteer Certificates etc. (if applicable)
REB Approvals For multi-site research, REB approval letters from research ethics boards in other jurisdictions where research is to be conducted. E.g. School Boards, Hospitals. (if applicable)
Research Contracts and Agreements For studies involving any external collaborations, services and/or research data or biological samples transferred outside of Holland Bloorview (if applicable)
Risk Assessment Documentation/Device Manuals For studies involving Class 2, 3, and 4 medical devices, assistive devices or related technologies. (if applicable)
Research Safety/Management Plans e.g. Community Safety Plan, Mental Health Research Safety (if applicable)
Certificates of Translation (if applicable)

Documents for Regulated Drug or Medical Device Trials (only)
Local Principal Investigator current curriculum vitae (updated within the last 12 months)
Research Team Training Certificates CITI Modules: GCP - Canada and Health Canada Division 5 – Drugs for Clinical Trials Involving Human Subjects (in addition to TCPS2, RCR, Privacy as noted above)
No Objection Letter (NOL)/Investigational Testing Authorization (ITA)
Investigator Brochure or Product Monograph For regulated drug trial submissions
Pharmacy Impact Approval For studies requiring pharmaceutical services at Holland Bloorview.